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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,838	03/30/2004	Theoharis C. Theoharides	2003133.125US10	3057
23483	7590	08/20/2009	EXAMINER	
WILMERHALE/BOSTON			WANG, SHENGJUN	
60 STATE STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02109			1617	
			NOTIFICATION DATE	DELIVERY MODE
			08/20/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/811,838	THEOHARIDES, THEOHARIS C.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-61 is/are pending in the application.
- 4a) Of the above claim(s) 45-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-44, 49-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Receipt of applicants' amendments and remarks submitted June 9, 2009 is acknowledged.

1. The terminal disclaimer filed on December 9, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US application 10/610,909 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Claim Rejections 35 U.S.C. 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 61 recites numerical ranges "150-600350-1200", "500-100025 250", and 25-250500 1000". It is unclear what the exactly ranges are claimed. The claim is indefinite as to the ranges recited therein.

#### ***Claim Rejections 35 U.S.C. 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 40, 43 and 49-51 and 61, are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio (WO 0097/21434), in view of Singh et al. (US 5,858,371), Nobile et al. (US 4,265,823) (in light of Dr. Duke's phytochemical and ethnobotanical database), Widyarini. et al.; and Oka et al. (JP 06016531).
7. Florio teaches an anti-inflammatory composition comprising chondroitin sulfate, polyunsaturated fatty acid. See, particularly, the abstract.
8. Florio does not teach expressly the employment of quercetin, olive kernel extract, and isoflavonoids, such as genistein and phenoxodiol.
9. However, Singh et al. disclosed that quercetin is known to have anti-inflammatory activity. See, particularly, col. 8, lines 25 to col. 10, line 51. Noblie et al. (US 4, 265, 823) disclosed that estrole is a steroid which displayed anti-inflammatory properties (col. 10, lines 20-37). The claims state 'olive kernel extract'. Giving the phrase its broadest interpretation within reason, lacking any specific definition in the Instant specification, it is deemed that an 'olive kernel extract' may be a crude extract, or an isolated phytochemical from the olive kernel (seed). Estrone is a compound endogenous to olive kernel (see for example, Dr. Duke's Phytochemical and Ethnobotanical Database\*, page 2 of internet print-out). Widyarini et al. teaches that isoflavonoids, such as phenoxodiol (dehydroequol), and genistein, are potent anti-inflammatory agents. See, particularly, the abstract. Oka et al. teaches that flavonoids and isoflavonoids, including genistein, are known to have anti-inflammatory activity. See, particularly, the abstract, the claims, paragraph [0028], table 5 and paragraph [0043].
10. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to make a composition comprising chondroitin, a

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extract of olive kernel, such as estrole, a flavonoid, such as quercetin, and isoflavonoids, such as genistein and/or phenoxodiol.

A person of ordinary skill in the art would have been motivated to make a composition comprising chondroitin, a extract of olive kernel, such as estrone, a flavonoid, such as quercetin, and isoflavonoids, such as genistein and/or phenoxodiol because each of the ingredients are known to have anti-inflammatory activity. It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of known anti-inflammatory agents sets forth prima facie obvious subject matter.

See In re Kerkhoven, 205 USPQ 1069.

The evidence of record shows that the subject matter as claimed is a combination of known components selected for their known properties as anti-inflammatory agent. A claim which unites elements with no change in their respective anti-inflammatory properties to yield a predictable result is not patentable in the absence of secondary considerations.

For over a half century, the [Supreme] Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ...obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

*KSR Int'l v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (2007).

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Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in treating any inflammatory condition including those conditions in prostate.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in claim 42, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Furthermore, it is well settled that the “intended use” of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161.

11. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

12. Claims 41, 42, 44, 52-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio (WO 0097/21434), in view of Singh et al. (US 5,858,371), Nobile et al. (US 4,265,823) (in light of Dr. Duke's phytochemical and ethnobotanical database), Widyarini. et al. and Oka et al. (JP 06-16531) for reasons set forth above and in further view of Ip et al.

13. The cited references do not teach expressly the employment chemotherapeutic agent, such as tamoxifen.

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14. However, Ip discloses that Tamoxifen is known to be useful for treatment of prostate cancer. See, particularly, the abstract.

15. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made, to further incorporate tamoxifen in the composition for treatment of prostate cancer patients who have inflammatory conditions.

One of ordinary skilled in the art would have been motivated to incorporate tamoxifen within the composition for treatment of prostate cancer because the composition is useful for treatment of inflammatory condition in prostate and tamoxifen is known to be useful for treatment of prostate cancer. The evidence of record shows that the subject matter as claimed is a combination of known components selected for their known properties as anti-inflammatory agents and chemotherapeutic agent. A claim which unites elements with no change in their respective properties to yield a predictable result is not patentable in the absence of secondary considerations.

For over a half century, the [Supreme] Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ...obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

*KSR Int'l v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (2007).

### ***Response to the Arguments***

16. Applicants' amendments and remarks submitted June 9, 2009 have been fully considered, but are not persuasive.

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Applicants contend that the cited references provide no teaching or suggestion with regard to the particular ratio recited in the claims. The arguments are found unpersuasive. Particularly, Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in claim 42, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Furthermore, it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161.

17. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

#### ***Allowable Subject Matters***

18. Following subject matter is allowable in view of the fact that with proper amount of olive kernel extract, the absorption of chondroitin sulfate substantially increased. See, paragraphs [0027]-[0029], example 17. However, the claims as pending do not recite the critical limitations of olive kernel extract, unrefined and has oleic acid-related acidity <3%, and water content <1%.

Claim 40      A composition for treating inflammatory components of a hormonally-dependent cancer, comprising, in therapeutically effective amounts, a sulfated



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proteoglycan, one or more flavonoid compounds, a-none or more isoflavonoid compounds, and olive kernel extract, wherein the ratio of the sulfated proteoglycan to the flavonoid ranges from 1:5 to 12:1, the ratio of the sulfated proteoglycan to the isoflavonoid ranges from 1:20 to 6:1, and the ratio of the sulfated proteoglycan to the olive kernel extract ranges from 1:24 to 6:7, wherein the olive kernel extract is unrefined and has oleic acid-related acidity <3%, and water content <1%.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/  
Primary Examiner, Art Unit 1617